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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,470	01/21/2004	Wei Shao	CL001204-DIV	1815

25748 7590 03/09/2006

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,470	SHAO ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-2 and 37-38 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 3 and 24-36 are being acted upon.

2. Applicant's amendment and remarks, filed 1/31/06, are acknowledged.

3. The objections to the abstract and title are withdrawn, in view of Applicant's amendment.

4. Applicants submission of the corrected CRF and sequence listing is acknowledged. The corrected CRF and sequence listing are acceptable.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 24-36 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) An isolated antibody that selectively binds to a "polypeptide" (Claim 3, 24, 56-36, and dependant claims 25-34).

B) "A composition comprising the antibody...and a pharmaceutically acceptable carrier" (Claims 31-34).

It is noted that applicant has not cited any support for the new claims in the specification. A review of the specification fails to reveal support for the new limitations.

Regarding A), at page 27, the specification discloses "the invention also provides antibodies that selectively bind to one of the peptides of the present invention, a protein comprising such a peptide.." The specification does not appear to

disclose antibodies to polypeptides, as now recited in the instant claims.

Regarding B), the specification as filed does not appear to provide a written description for the limitation of claims 31-34, where the antibody is part of a composition with a pharmaceutically acceptable carrier.

Applicant's arguments, filed 1/31/06, have been fully considered but they are not persuasive.

With regard to A), Applicant argues that the term "polypeptide" and "peptide" are used synonymously. However, purely in response to Applicant's arguments, it is noted that peptides can be considered to be small proteins of less than 50 amino acids (see, for example, Wikipedia Encyclopedia). In contrast, polypeptides are peptides of between 10 and 100 amino acids (see, for example, American Heritage Dictionary definition). Therefore, the terms "polypeptide" and "peptide" have different scopes, and are not in fact synonymous terms.

With regard to B), Applicant argues that original claim 17 which recites "a pharmaceutical composition comprising an agent… and a pharmaceutically acceptable carrier" provides support for Claims 31-34, since an "agent" can be an antibody. However, the term "agent" has a much broader scope than the term "antibody", and as such does not provide adequate written description for an "antibody… and a pharmaceutically acceptable carrier", as recited in claims 31-34. In this instance "agent" can be considered to be a genus, while antibody is a sub-genus. It is well established that the disclosure of a genus does not provide adequate description for a sub-genus or species within said genus.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tighilet et al. as evidenced by Karls et. al.

As set forth previously, Tighilet teaches an antibody specific for residues 521-540 of mouse calcium/calmodulin dependent protein kinase Iβ subunit (CaMKII-β-see page 284). As evidenced by Fig. 1 of Karls, residues 521-540 of mouse

CAMKII-β correspond exactly to residues 495-514 of SEQ ID NO: 2 of the instant application. Therefore said antibody would inherently bind to a polypeptide consisting or comprising SEQ ID NO: 2.

Applicant's arguments filed 1/31/06 have been fully considered but they are not persuasive.

Applicant argues that the Examiner has cited a reference that teaches an antibody that may possibly or probably selectively bind to the polypeptides of SEQ ID NO: 2.

The Examiner never contented that the referenced antibodies would "possibly or probably" bind to SEQ ID NO:2 of the instant application, as Applicant argues. Rather, the rejection of record states that the antibodies taught by Tighilet would bind to a polypeptide consisting or comprising SEQ ID NO: 2.

Applicants further argues that the antibody of Tighilet does not necessarily bind to polypeptides of SEQ ID NO: 2 because different epitopes must necessarily exist in the polypeptide of SEQ ID NO: 2 compared with the protein of Tighilet.

It is irrelevant if some of the epitopes of the protein of Tighilet differ from SEQ ID NO: 2. The fact remains that the epitope that the referenced antibodies are specific for is present in SEQ ID NO: 2, and therefore the antibodies would necessarily bind to a polypeptide consisting or comprising SEQ ID NO: 2.

Applicant also argues that the Examiner has not provided any evidence that the referenced antibodies must necessarily bind to polypeptides of SEQ ID NO: 2.

Antibodies are sequence specific. Absent a showing that the antibody would not bind the same sequence, the antibody does bind the sequence. It is noted that the office does not have a laboratory to test the referenced antibodies. It is applicant's burden to show that the referenced antibodies do not bind to SEQ ID NO: 2. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tighilet et. al in view of Gavilondo et. al.

As set forth previously, The teachings of Tighilet are described above.

Tighilet does not teach a monoclonal antibody, an antibody coupled to a detectable substance, a composition comprising the antibody and a pharmaceutically acceptable carrier, or an isolated antibody fragment.

Gavilondo teaches the usefulness of monoclonal antibodies (see pg. 128) and antibody fragments (Table 1) for therapeutic, and diagnostic purposes (i.e. as compositions in a pharmaceutically acceptable carrier). In addition, Gavilondo teaches that antibodies can be fused with enzymes (i.e. detectably labeled-see pg. 135).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a monoclonal antibody, a composition thereof, an antibody fragment, or detectably labeled antibody as taught by Gavilondo to CAMKII-β protein as taught by Tighilet. The ordinary artisan at the time the invention was made would have been motivated to do so, since monoclonal antibodies, compositions thereof, labeled antibodies, and antibody fragments are extremely useful as diagnostic and therapeutic agents (see Gavilondo pgs. 128, 135-136, and Table 1). Moreover, one of ordinary skill in the art would have expected to succeed in generating said antibodies.

Applicant's arguments filed 1/31/06 have been fully considered but they are not persuasive.

Applicant argues that the Tighilet, even in combination with Gavilondo, neither anticipates nor makes obvious claims 25-36 due to the different epitopes that exist because of the extensive amino acid sequence difference in the protein of Tighilet compares to SEQ ID NO: 2.

However, as discussed above, the antibodies taught by Tighilet do anticipate and make obvious the instantly claimed antibodies due to the fact that SEQ ID NO: 2 comprises the exact same epitope the referenced antibodies are specific for.

8. No claim is allowed.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
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February 22, 2006

3/6/06
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PRIMARY EXAMINER